

R E M A R K S

Claims 1-11, 13-22, and 24-26 are in the application. Claim 24 has been withdrawn as being drawn to a non-elected invention. Claims 12 and 23 were previously cancelled. In the Office Action, Claims 2-5, 7, 15-19, and 26 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description and enablement requirements. Claims 25 and 26 were objected to for having alleged improper claim identifiers, but Claim 25 was indicated as otherwise allowable.

Claim 4 is amended to change the dependence from Claim 2 to Claim 1. Claim 15 is amended solely to correct an unintentional grammatical error (the removal of a comma). No new matter is added into the case by the amendments.

Applicants would like to thank the Examiner for the indication that Claims 1, 6, 8-11, 13, 20, 22, and 25 are deemed allowable.

All rejections and objections are respectfully traversed. Reconsideration and favorable action are requested in light of the amendments and remarks presented herein. In this regard, Applicants note that no claim is rejected on art. All outstanding issues are Section 112 formalities, for which Applicants believe the present amendment and remarks more than adequately address without requiring any significant further work or examination burden by the Examiner. Hence, Applicants believe these amendments and remarks should definitely be entered and considered and deemed sufficient to place the case in condition for allowance.

A. The Objection to Claims 25 and 26 is Now Moot.

The claims have been amended with respect to the claim identifiers including Claims 25 and 26. Accordingly, the objection to Claims 25 and 26 is now overcome. Applicants respectfully request reconsideration and withdrawal of the objection, and allowance of Claims 25 and 26.

B. Claims 2-5, 7, 15-19, and 26 Comply With 35 U.S.C. §112.

Claims 2-5, 7, 15-19, and 26 stand rejected as allegedly failing to comply with the written description and enablement requirements of 35 U.S.C. §112. It is believed this rejection is not well taken. The specification fully describes how to modify a DNA sequence coding for hG-CSF,

the native gene of which is defined by SEQ ID NO:3, as called for in independent Claim 2. The claim calls for making the modifications to particular segments of the gene, as taught on pages 8-10 of the specification, where specific replacements in the gene sequence of SEQ ID NO:3 are spelled out in some detail.

In particular, the specification and Claim 2 break up SEQ ID NO:3 into four segments (Segments I-IV). Pages 8-10 of the specification describe not only the modifications made in each segment, but also the techniques used to make the modifications. As one example of a modified gene in accordance with Claim 2, Example 1, on pages 13-16 of the specification, details a step by step construction of an optimized hG-CSF gene, Fopt5 (SEQ ID NO:1), a modified version of SEQ ID NO:3, which is the subject of Claim 2. With knowledge of this inventive modified sequence, many other variants within the scope of the Claim 2 sequence become apparent, and it would readily be within the ordinary skill of one in the art to produce such variants, based on Applicants' disclosure. The scope of Claim 2 is intended to cover such variants, as long as one or more of the recited modifications are made in the identified segments of SEQ ID NO:3. Accordingly, a person of ordinary skill in the art would very plainly be able to make and use the claimed invention based on the disclosure in the specification, without undue experimentation. Thus, Claim 2 is fully enabled by the specification.

It appears the rejection of Claim 2 is based on an improper or erroneous attempt to draw subject matter from Claim 4 into Claim 2. Claim 4 recites a limitation that the sequence provides an expression level of G-CSF of at least 50%, as quantified by staining protein bands after separation by SDS-PAGE. The Office Action asserts that Claim 2 is somehow deficient in regard to this limitation, but this is incorrect because Claim 2 does not specify an expression level of at least about 50%. Claim 2 merely calls for a modified DNA sequence coding for hG-CSF, with specific modifications in Segments I-IV as claimed and taught in the specification.

Furthermore, Claim 4 is amended herein so as to depend from independent Claim 1, not Claim 2, and thus is fully enabled by the example data in Table 1 on page 19 of the specification and in Table 2 on page 21 of the specification. The specification describes and enables the subject matter of achieving at least 50% expression for SEQ ID NO:1 called for in Claim 1.

Again, with regard to both Claims 1 and 2, Applicants wish to note further that, as explained in *In re Grimme*, 124 USPQ 499 (CCPA 1960), a single specific example can be sufficient disclosure for claiming a genus. The CCPA rule similarly in the case of *In re Robbins*,

166 USPQ 552 (CCPA 1970), where it held that “mention of representative compounds encompasses by generic claim language clearly is not required by §112 or any other provision of the statute.” Applicants have provided an example of how to make a particular optimized gene, Fopt5, described by SEQ ID NO:1, and it is believed a person of skill in the art can readily apply the concepts described in the specification to further modify the native gene of SEQ ID NO:3, as called for in Claim 2, for efficient expression in *E. coli*, and therefore practice the subject matter as claimed without undue experimentation.

Since independent Claim 2 is shown to be allowable, dependent Claims 3, 5, 7, 15-19, and 26 are also allowable. Claim 4 is allowable because the dependency has been changed to Claim 1 as described above. Accordingly, reconsideration and allowance of Claims 2-5, 7, 15-19, and 26 are hereby respectfully requested.

#### CONCLUSION

Applicants respectfully submit that a full and complete response to the Office Action is provided herein, and that the application is now fully in condition for allowance. Action in accordance therewith is respectfully requested.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 122355.

Respectfully submitted,  
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